

cooling the lysis mixture under conditions that make it possible to isolate or hybridize the nucleic acids to be isolated or detected.

### **REMARKS**

Applicants respectfully submit that entry of this Amendment is proper under 37 C.F.R. § 1.116 since this Amendment: (a) does not raise any new issue regarding further search and/or consideration since it clarifies issues already discussed in the prosecution; (b) does not present any additional claims; and (c) places the application in better form for appeal, should an appeal be necessary. Entry of the Amendment is thus respectfully requested. Accordingly, reconsideration of the application in view of the following remarks is respectfully requested.

Claims 13-35 are pending.

Claim 13 is again rejected under 35. U.S.C. § 102(e) as being anticipated by Reeve (U.S. Patent No. 5,523,231) (June 4, 1996). The Examiner takes the position that the Reeve reference shows all of the limitations of the rejected claims.

Applicant respectfully traverses the rejection. Applicant respectfully refers the Examiner to the Reeve reference, specifically to Precipitation of Bacteriophage and other Viruses from Solution in column 6, lines 4-33. As the Applicant indicated in his previous Response, this embodiment seems to be the most comparable to the present invention because it most closely resembles the isolation of nucleic acids from substances which can be considered "biological compartments."

Again summarizing the description in column 6, lines 4-33, magnetic beads are added to a solution of bacteriophage or virus particles, and then a magnetic field is applied to draw those particles out of solution. The first solution is removed. A second solution is added in the absence of a magnetic field. The magnetic field is reapplied to

draw out the magnetic beads, leaving the nucleic acids in solution. According to Figure 2, the purified dissolved particles are thereafter ready for DNA extraction.

The Reeve reference does not contain the same elements as claim 13, and therefore it does not anticipate. Claim 13 is distinct in two ways: 1) it introduces a "shaking" step within the broader "re-suspending" step, and 2) it introduces a "lysis" step.

The Examiner cited a "shaking" step in the Reeve reference. However, it appears that the Examiner was incorrect in his application of this cite. The reference only discloses a "mixing" step in the embodiment entitled "Alcohol Precipitation of Nucleic Acid Molecules." See column 4, lines 8-44.

Applicant notes that the "shaking" step, to which the Examiner refers, is not disclosed in the embodiment that most compares to the present invention. See column 6, lines 4-33. On the contrary, claim 13 expressly claims this step. In fact, page 15 paragraph 4 of the present specification indicates that shaking is an "important" feature of this invention. Hence, the "re-suspending" step in claim 13 may be distinguished from the "re-dissolving" step in the Reeve reference on this basis.

To further distinguish claim 13 from the reference, Applicant amends the "shaking" step in claim 13 to recite "in the absence of the magnetic force." This amendment is fully supported by explicit language in the Specification at page 16, paragraph 3.

Furthermore, unlike the closest embodiment disclosed in the Reeve reference, claim 13 contains a "lysis" step. According to Figure 2, the Reeve reference discloses that the once the magnetic beads are drawn from the solution, the purified virus particles are ready for DNA extraction. The reference does not specifically disclose

lysing the particles and isolating the nucleic acids from the lysis mixture, as claimed in claim 13.

Claim 34 is once again rejected under 35. U.S.C. § 102(e) as being anticipated by Reeve. The Examiner takes the position that the Reeve reference shows all of the limitations of the rejected claims.

The Applicant respectfully traverses this rejection. In fact, Applicant's argument above, supporting the patentability of claim 13, also applies to claim 34. Applicant reaffirms his contention that the Examiner incorrectly applies the Reeve embodiment entitled Precipitation of Bacteriophage and other Viruses from Solution (column 6, lines 4-33), which is not comparable to claim 34 of the present invention.

Moreover, as in claim 13, Applicant amends the "shaking" step in claim 34 to recite "in the absence of the magnetic force." This amendment is fully and explicitly disclosed in the Specification. See the Specification, page 16, paragraph 3.

Additionally, claim 34 is different from the Reeve reference because it contains the additional steps of warming the lysis mixture and then cooling the lysis mixture to assist in the isolation of the nucleic acids. The Reeve reference only discloses a "chilling" step (column 6, lines 17-18) to assist the aggregation of nucleic acids to the magnetic beads. The reference does not include a "warming" step.

Applicant respectfully submits that the dependent claims are patentable by virtue of their being dependent on the patentable features otherwise claimed. The Reeve patent did not disclose or suggest the independent claims of the present invention, and therefore the dependent claims are also patentable.

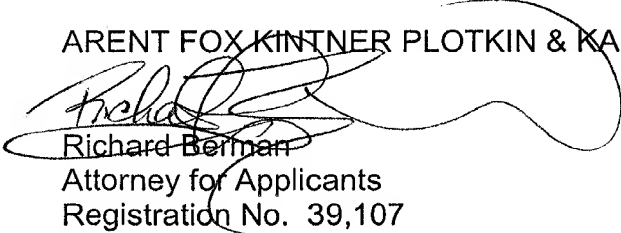
In view of the foregoing, reconsideration of the application, withdrawal of the outstanding rejections, allowance of claims 13-35, and the prompt issuance of a Notice of Allowability are respectfully solicited.

Should the Examiner believe anything further is desirable in order to place this application in better condition for allowance, the Examiner is requested to contact the undersigned at the telephone number listed below.

In the event this paper is not considered to be timely filed, the Applicants respectfully petition for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to counsel's Deposit Account No. 01-2300, **referencing docket number 101614-00001**.

Respectfully submitted,

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Enclosure: Marked-Up Copy of the Claims



MARKED-UP COPY OF THE CLAIMS

13. (Twice Amended) A method of isolating nucleic acids from biological compartments of a fluid sample comprising the steps of:

incubating the sample in a sample processing vessel with magnetic particles which magnetic particles are capable of binding with the biological compartments;

positioning at least one magnet towards the sample processing vessel to hold the magnetic particles against an inside wall of the sample processing vessel by magnetic force;

removing the remaining fluid, from which the biological compartments have been separated, from the sample processing vessel;

introducing a second fluid into the sample processing vessel;

resuspending the magnetic particles in the second fluid by eliminating the magnetic force which held the magnetic particles against the inside wall of the sample processing vessel, and shaking the sample processing vessel in the absence of the magnetic force;

lysing the biological compartments to form a lysis mixture; and

isolating the nucleic acids from the lysis mixture.

34. (Twice Amended) A method of isolating nucleic acids from biological compartments of a fluid sample comprising the steps of:

incubating the sample in a sample processing vessel with magnetic particles which magnetic particles are capable of binding with the biological compartments;

positioning at least one magnet towards the sample processing vessel to hold the magnetic particles against an inside wall of the sample processing vessel by magnetic force;

removing the remaining fluid, from which the biological compartments have been separated, from the sample processing vessel;

introducing a second fluid into the sample processing vessel;

resuspending the magnetic particles in the second fluid by eliminating the magnetic force which held the magnetic particles against the inside wall of the sample processing vessel, and shaking the sample processing vessel in the absence of the magnetic force;

lysing the biological compartments to form a lysis mixture; and

warming the lysis mixture; and

cooling the lysis mixture under conditions that make it possible to isolate or hybridize the nucleic acids to be isolated or detected.